

COLORADO STATE BOARD OF PHARMACY
September 20, 2012

Minutes

The Colorado State Board of Pharmacy meeting was convened by President Paul Limberis, RPh, at approximately 8:36 a.m. on Thursday, September 20, 2012 at 1560 Broadway, Conference Room 110 D, Denver, CO 80202. Notice of this meeting was given in accordance with Division of Registrations Policy Number 80-17.

Board members attending were: Jeannine Dickerhofe, RPh; Heather Hawker, JD; Donald Johnson, RPh; Paul Limberis, RPh; Ginny Orndorff, MBA; Armand Potestio, RPh; and Luis Rivera-Lleras, RPh.

Staff members attending were: Wendy Anderson, RPh, Program Director; Chris Gassen, RPh, Chief Inspector; and Linda Acosta, Complaint and Licensing Specialist. Also present was Jack Wesoky, Senior Assistant Attorney General, to advise the Board.

APPROVAL OF THE MINUTES

The Board approved of the minutes from the July 19, 2012 meeting.

APPEARANCES

Scotti Russel, Government Affairs Director for the National Association of Boards of Pharmacy (NABP), appeared before the Board to discuss NABP's Prescription Monitoring Program InterConnect (PMPi) program. Ms. Russell also discussed NABP's Pharmacist Assessment for Remediation Evaluation (PARE) assessment examination that boards of pharmacy may use when making decisions regarding pharmacist practice deficiencies that are due to noncompliance with pharmacy practice standards.

After careful consideration of the available information, the Board voted unanimously to allow Colorado's Prescription Drug Monitoring Program to become a participant in NABP's PMP InterConnect program. The Board noted the PARE assessment examination and determined more information would be needed.

ADDITIONS

The following cases were added to the agenda for the Board's review: Cases 2012-2697, 2012-5655, 2012-5657, 2012-5663, 2012-5665, 2012-5668, and 2012-5801.

REPORTS

President's Remarks

Paul Limberis stated that the next NABP District 8 meeting will be held in Little Rock, AR in October 2012.

Program Director's Report

Ms. Anderson presented a proposed amendment to Board Policy 10-1 (Protocols for Complaints) to address the Program Director's handling of significant dispensing errors discovered during the course of routine pharmacy inspections. After careful consideration, the Board voted unanimously to approve of the proposed amendment.

Ms. Anderson presented a proposal to the Board to repeal Board Policy 20-1 (Administrative Approval of Preceptors), as the function of preceptors no longer exists statutorily. After careful consideration, the Board voted unanimously to repeal Policy 20-1.

The Board considered an amendment to Board Rules 15.01.11 and 15.01.14 which, as proposed, would extend the period of time a prescription drug wholesaler would have to submit an application and fee detailing the name of a new designated representative from the time the previous designated representative ceased the position from 14 calendar days to 30. After careful consideration, the Board voted unanimously to move the proposed amendments to a future rules hearing.

Ms. Anderson presented information regarding House Bill 12-1052 regarding the Collection of Health Care Work Force Data and what it means for pharmacist license renewals. While the online renewal process will ask pharmacists to voluntarily answer questions related to their respective types of practice settings, a failure to answer such questions will not hold up license renewal.

Ms. Anderson discussed with the Board various versions of electronic interstate connectivity of prescription drug monitoring programs currently in use in the United States. The Board noted the information.

Ms. Anderson presented the Board proposed amendments to the Board's rules that were a result of the Pharmacy Sunset bill. In addition, Ms. Anderson presented to the Board proposed amendments and additions to the Board's rules that resulted from recommendations of the Pharmacy Intern Task Force, Hospital Satellite Task Force, Other Outlet Task Force, and Remote Order Entry Task Force. Lastly, Ms. Anderson presented the Board with proposed additions to the Board rules that resulted from the Specialized Prescription Drug Outlet Task Force. She stressed to the Board that this task force could not come to a consensus regarding the legislative intent behind a specialized prescription drug outlet registration (specifically, whether the specialized prescription drug outlet registration is to be assigned to an existing prescription drug outlet or to an automated dispensing device located within a long term care facility). In doing so, Ms. Anderson also provided the Board proposed language governing specialized prescription drug outlets offered by Timothy Mead, a member of that task force. After careful consideration of the available information, the Board voted unanimously to move all of the amendments and additions to its rules, as proposed by Ms. Anderson, to the November 7, 2012 scheduled rules hearing.

Ms. Anderson updated the Board regarding the following changes that either have impacted or will impact the Pharmacy Board's operations:

- The Prescription Drug Monitoring Program's transition of vendors was successful;
- The Department of Regulatory Agencies is requiring each Board/Program to set a regulatory agenda for next year;
- The Division of Professions and Occupations changed licensing systems effective July 1, 2012;
- Each Board staff members email address will change effective October 9, 2012; and

- Each Board/Program will be transitioning to a new website in October 2012.

Colorado Pharmacists Society (CPS) – Paul Limberis, RPh

CPS, in conjunction with Health Resources and Services Administration and the two Colorado schools of pharmacy will be planning, coordinating and participating in the Colorado Pharmacists Summit on September 24, 2012 entitled “Strategizing Action for Integration and Leadership” or SAIL. The purpose of this conference is to bring stakeholders together to explore the various ways to engage Colorado pharmacists in the emerging opportunities provided by health care reform, including the patient centered medical home.

Planning has already begun for the 2013 CPS Annual Winter CE Seminar, January 13-16, 2013 at the Vail Cascade in Vail, CO. Fifteen hours of ACPE-approved CE will be offered.

Governor’s Expert Emergency Epidemic Response Committee (GEEERC) – Paul Limberis, RPh

Paul Limberis reported that the GEEERC met on Thursday, August 9, 2012.

The first item on the agenda included a Bio Watch Exercise Conversation. A question was raised as to if the GEEERC should be on call after Phase I sampling occurs, or when the bio watch sensor goes off, should notification of the GEEERC be moved up prior to Phase I sampling. The GEEERC voted to bump up notification of the GEEERC members prior to sampling in the event of a bio watch sensor activation.

The next item of discussion concerned the GEEERC membership as outlined in the state Act. The committee approved that functional back-ups will have voting privileges, when the primary member is not in attendance. This will be added to the bylaws. It was also approved to allow members to remotely vote by HSIN network or teleconference. This was also added to the bylaws.

It was noted under public comment that a case of anthrax in cattle had been identified in northeast Colorado. Vaccine was provided to the ranch and other neighboring ranches. This was the first case reported in 31 years. No meat was introduced into the food supply. The Office of Preparedness introduced Melanie Simons as the new Strategic National Stockpile coordinator.

The next meeting of the GEEERC is planned for Thursday, November 8, 2012.

Intern & School Relations – Jeannine Dickerhofe, RPh

Dr. Catherine Jarvis, Assistant Dean of the University of Colorado Denver School of Pharmacy, reported that the school is utilizing new curriculum, and that the school now drug tests each of the students every year.

No report was provided by the Regis University School of Pharmacy.

Legislation - Jeannine Dickerhofe, RPh

No report was provided.

Inspectors

Vail Valley Pharmacy, PDO 839

The Board reviewed an Agenda Memorandum from Inspector Susan Martin regarding a routine inspection of Vail Valley Pharmacy. After careful consideration of the available information, the Board voted unanimously to refer the matter to Executive Session.

After Executive Session, the Board voted unanimously to initiate a case against Vail Valley Pharmacy, and then dismiss the case. The Board found that there was no reasonable cause to warrant further action at this time.

OLD BUSINESS

Stipulations

Lynda Budman, RPH 15314 & Case 2006-4032

The Board reviewed an Agenda Memorandum from Mr. Gassen regarding Ms. Budman's Stipulation for Cessation of Practice she entered into with the Board effective December 16, 2010. After careful consideration of the available information, the Board voted unanimously to refer the matter to Executive Session.

Tyson Gutherless, RPH 16762 & Case 2012-4287

The Board reviewed an Agenda Memorandum from Mr. Gassen regarding a Board Order Pursuant to Section 12-22-605(3) C.R.S. the Board issued to Mr. Gutherless effective May 21, 2012. The Board voted unanimously to dismiss the case as being without merit.

Daniel Wylie, RPH 15265 & Case 2012-3849

The Board reviewed an Agenda Memorandum from Mr. Gassen regarding Mr. Wylie and a Stipulation for Interim Cessation of Practice he entered into with the Board effective July 31, 2012. After careful consideration of the available information, the Board voted unanimously to refer the case to Executive Session.

After Executive Session, the Board voted unanimously to summarily suspend Mr. Wylie's license for willful violation if he fails to sign a suspension stipulation or relinquish his license within ten business days.

NEW BUSINESS

Complaints

Aubermann, John, RPH 11244

2012-4485

The Board voted unanimously to refer the case to Executive Session.

After Executive Session, the Board voted unanimously to dismiss this case as being without merit. The Board, however, recommended that the complainant may wish to consider filing a complaint with the U.S. Department of Health & Human Services.

Aubermann, John, RPH 11244

2012-4486

The Board voted unanimously to refer the case to Executive Session.

After Executive Session, the Board voted unanimously to dismiss this case as being without merit.

B & B Pharmacy, PDO 13-1

2012-4820

The Board voted unanimously to dismiss the complaint as being without merit. The Board, however, recommended that the complainant may wish to consider filing a complaint with the U.S. Department of Health & Human Services.

Berthoud Drug, PDO 8-1

2012-3999

The Board voted unanimously to dismiss the complaint as being without merit.

Foreman, Karl, RPH 15776

2012-4001

The Board voted unanimously to dismiss the complaint as being without merit.

Bjorhus, Martina, RPH 16794

2012-3959

The Board voted unanimously to refer the case to Executive Session.

After Executive Session, the Board voted unanimously to dismiss the case. The Board found that there was no reasonable cause to warrant further action at this time.

Colcord, Don, RPH 10164

2012-4194

The Board voted unanimously to refer the case to Executive Session.

After Executive Session, the Board voted unanimously to issue a Letter of Admonition for violations of the Pharmacists, Pharmacy Businesses, and Pharmaceuticals Act.

Coram Specialty Infusion Services, PDO 37-24

2012-4712

The Board voted unanimously to refer the case to Executive Session.

After Executive Session, the Board voted unanimously to dismiss the case. The Board found that there was no reasonable cause to warrant further action at this time.

Dower, Kim, RPH 13772

2012-5801

The Board voted unanimously to refer the case to Executive Session.

After Executive Session, the Board found that the public health, safety, or welfare imperatively required emergency action and voted unanimously to summarily suspend Ms. Dower's pharmacist license should she fail to enter into an interim cessation of practice agreement with the Board by 3:00 p.m. on October 1, 2012. The Board also voted

unanimously to order Ms. Dower to obtain an evaluation pursuant to C.R.S. 12-42.5-204(3) from the Pharmacy Peer Health Assistance Diversion Program.

Drug Depot, Inc., OSP 5618

2012-3952

The Board voted unanimously to refer the case to Executive Session.

After Executive Session, the Board voted unanimously to dismiss the case. The Board found that there was no reasonable cause to warrant further action at this time.

Edmisten, Daniel, RPH 15052

2012-5095

The Board voted unanimously to refer the case to Executive Session.

After Executive Session, the Board voted unanimously to table further consideration of this case pending receipt of additional information.

Emmonds, Todd, RPH 16591

2012-4771

Donald Johnson, RPh, recused.

The Board voted unanimously to refer the case to Executive Session.

Love, Lynda, RPH 12571

2012-4930

The Board voted unanimously to dismiss the complaint as being without merit.

McGrew, John, RPH 13229

2012-4552

The Board voted unanimously to refer the case to Executive Session.

After Executive Session, the Board voted unanimously to dismiss the case. The Board found that there was no reasonable cause to warrant further action at this time.

Osieczanek, Craig, RPH 12797

2012-5180

The Board voted unanimously to refer the case to Executive Session.

After Executive Session, the Board voted unanimously to dismiss the complaint as being without merit.

PetMed Express, Inc., OSP 5087

2012-4490

The Board voted unanimously to dismiss the complaint as being without merit.

Professional Flu Clinics, Inc., WHI 6028

2012-4541

The Board voted unanimously to refer the case to Executive Session.

Stanford, Oliver, RPH 14507

2012-4871

Jeannine Dickerhofe, RPh, recused.

The Board voted unanimously to refer the case to Executive Session.

After Executive Session, the Board voted to table further consideration of this case pending receipt of additional information. The Board also voted unanimously to initiate a separate case against Cornell Prescription Pharmacy (PDO 40) for an alleged lack of documentation detailing the identity of the pharmacist conducting the initial interpretation on a prescription order.

Stofer, Carole, RPH 12498

2012-5099

Paul Limberis, RPh, recused.

The Board voted unanimously to refer the case to Executive Session.

After Executive Session, the Board voted unanimously to dismiss the case. The Board found that there was no reasonable cause to warrant further action at this time.

Walgreen Pharmacy # 5645, PDO 82-8

2012-4952

Donald Johnson, RPh, recused.

The Board voted unanimously to refer the case to Executive Session.

Wal-Mart Pharmacy # 10-3020, PDO 845

2012-5663

The Board voted unanimously to dismiss this case as being without merit.

Wal-Mart Pharmacy # 10-3125, PDO 849

2012-5657

The Board voted unanimously to dismiss this case as being without merit.

Wal-Mart Pharmacy # 10-3126, PDO 846

2012-5665

The Board voted unanimously to dismiss this case as being without merit.

Wal-Mart Pharmacy # 10-3127, PDO 848

2012-5655

The Board voted unanimously to dismiss this case as being without merit.

Wal-Mart Pharmacy # 10-5668, PDO 847

2012-5668

The Board voted unanimously to dismiss this case as being without merit.

LICENSING/REGISTRATION

AmerisourceBergen, Out-of-State Prescription Drug Wholesaler Applicant

The Board reviewed an Agenda Memorandum from Ms. Acosta regarding AmerisourceBergen's application for out-of-state prescription drug wholesaler registration. After careful consideration of the available information, the Board voted unanimously to issue the registration.

MISCELLANEOUS

Correspondence, etc.

American Veterinary Medical Association (AVMA)

The Board noted the information, and directed its staff to send correspondence back to AVMA stating that existing laws and rules regulate the concerns detailed in the correspondence and that should veterinarians or a pet's owner have concerns about a pharmacy's or pharmacist's action, they can file a complaint and the Board will investigate the matter.

Pharmacy Peer Health Assistance Diversion Program 4th Quarter Report

The Board noted the information.

Referral from the Colorado Board of Dental Examiners

After careful consideration of the available information, the Board was unable to determine if the Prescription Drug Monitoring Program was inappropriately accessed and therefore, voted unanimously not to act on the information.

Anonymous Complaint Dated August 3, 2012

After careful consideration of the available information, the Board voted unanimously not to act on the information.

Ronald E. Lidderdale, RPH 12456

After careful consideration of the available information, the Board voted unanimously to refer the matter to Executive Session.

After Executive Session, the Board voted unanimously to initiate a case against Mr. Lidderdale's pharmacist license, and then dismiss the case. The Board found that there was no reasonable cause to warrant further action at this time.

Request from the Walgreen Company to Amend Board Rule 21.00.00

Donald Johnson, RPh, recused.

The Board reviewed a request from the Walgreen Company to amend Board Rule 21.00.00 to exclude the flavoring of prescriptions from being considered compounding. After careful consideration of the available information, the Board voted unanimously to refer the matter to Executive Session.

After Executive Session, the Board voted unanimously to refer the request to its 2013 regulatory agenda for consideration.

Center Pet Pharmacy, OSP 5822

After careful consideration of the available information, the Board voted unanimously not to act on the information.

Request from King Soopers / City Market to Clarify Board Rule 5.01.31

The Board considered a request from King Soopers/City Market Pharmacies for the Board to clarify Board Rule 5.01.31(a)(1) and its affect on a locked door separating pharmacy's counseling room and its compounding/dispensing area. After careful consideration of the available information, the Board voted unanimously to table further consideration of this request pending receipt of additional information.

Inquiry from Silvergate Pharmaceuticals, Inc.

The Board considered an inquiry from Silvergate Pharmaceuticals in Greenwood Village, CO regarding the requirements of Board licensure. Silvergate Pharmaceuticals does not manufacture, store, or distribute prescription drugs but rather, only facilitates such actions by contracting with others to perform them. After careful consideration of the available information, the Board determined that, based upon the nature of Silvergate Pharmaceuticals' activity as described above, Silvergate Pharmaceuticals does not need to be licensed as a prescription drug wholesaler with the Board.

Request from Brandeis University for Research Agreement for Prescription Drug Monitoring Program ("PDMP") Data Agreement

The Board considered a request from Brandeis University for a research agreement for information from the Prescription Drug Monitoring Program ("PDMP"). After careful consideration of the available information, the Board voted unanimously to refer the matter to Executive Session.

After Executive Session, the Board voted unanimously to deny the request because it would violate Colorado law.

EXECUTIVE SESSION

At 12:35 p.m., Board President Paul Limberis, R.Ph. moved that the Board enter into Executive Session.

The motion was seconded. The vote was unanimous with five votes approving the motion to go into Executive Session and none opposing.

The Board exited Executive Session at 3:00 p.m.

Open Session

Case 2012-4339

Donald Johnson recused.

The Board voted unanimously to issue a Letter of Admonition for violations of the Pharmacists, Pharmacy Businesses, and Pharmaceuticals Act.

Case 2012-4344

Donald Johnson recused.

The Board voted unanimously to table further consideration of this case pending receipt of additional information. The Board also voted unanimously to initiate a separate case against Walgreen Pharmacy # 5645 (PDO 82-8) for alleged issues pertaining to the packaging of drugs.

Case 2012-4461

Donald Johnson recused.

The Board voted unanimously to issue a Letter of Admonition for violations of the Pharmacists, Pharmacy Businesses, and Pharmaceuticals Act.

Case 2012-4746

The Board voted unanimously to issue a Letter of Admonition for violations of the Pharmacists, Pharmacy Businesses, and Pharmaceuticals Act.

Case 2012-5146

The Board voted unanimously to issue a Letter of Admonition for violations of the Pharmacists, Pharmacy Businesses, and Pharmaceuticals Act.

ADJOURNMENT

The Board adjourned at 3:15 p.m.

Approved by Paul Limberis, R.Ph., President Date: December 10, 2012